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14/45  
**PATENT**

Docket No. 350013-71

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**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

**In Re Application Of:**

Colin Watts

**Serial Number:** 09/646,950

**Filing Date:** December 8, 2000

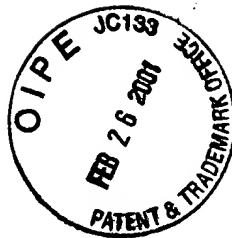
**Entitled: USE OF INHIBITORS OF  
MAMMALIAN ASPARAGINYL ENDOPEPTIDASE  
FOR THERAPY OF AUTOIMMUNE DISEASE**

**SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT**

Sir:

In accordance with 37 C.F.R. § 1.56, the references listed on the attached Form PTO-1449 are being brought to the attention of the Examiner for consideration in connection with the examination of the above-identified patent application. Copies of the cited documents are enclosed. References AF, AG, FI, GA, GB, GC, GD, GE and GF are herein disclosed for the first time. Applicant previously filed an Information Disclosure Statement listing all other enclosed documents as being "on order".

SERIAL No.: 09/646,950



DOCKET No. 350013-71

The filing of this Supplemental Information Disclosure Statement shall not be construed as a representation that a search has been made (37 C.F.R. § 1.97(g)), as an admission that the information cited is, or is considered to be, material to patentability, or that no other material information exists.

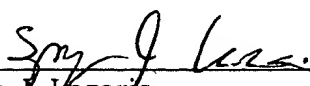
The filing of this Supplemental Information Disclosure Statement shall not be construed as an admission against interest in any manner.

**CONCLUDING REMARKS**

It is respectfully requested that the examiner indicate consideration of the cited references by returning a copy of the attached form PTO-1449 with initials or other appropriate marks with the initial Office Action, and that the references be made of record as cited references in the application.

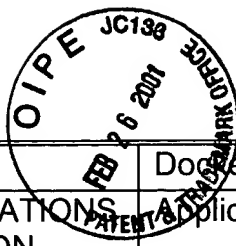
Respectfully submitted,

Date: February 21, 2001

  
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<b>FORM PTO-1449 (Modified)</b>				Docket No.: 350013-71		Serial No.: 09/646,950	
LIST OF PATENTS AND PUBLICATIONS FOR APPLICANT'S INFORMATION DISCLOSURE STATEMENT				Applicants: Colin Watts			
				Filing Date: Sept. 25, 2000		Art Unit:	
<b>UNITED STATES PATENT DOCUMENTS</b>							
*Exr's. Inits.	Ref.	Patent No.	Date	Name	Class	Sub Class	Filing Date (if applic- able)
	AA						
	AB						
<b>FOREIGN PATENT DOCUMENTS</b>							
Exr's. Init.	Ref	Document No.	Date	Country	Class	Sub	Translation? Yes No
	AC	WO 91/06571	16.05.91	PCT			
	AD	WO 94/24281	27.10.94	PCT			
	AE	WO 97/40066	30.10.97	PCT			
	AF	EP 0430645B1	27.11.90	EPO			
	AG	EP 0478602B1	20.06.90	EPO			
<b>OTHER REFERENCES (Including Author, Date, Title, Pertinent Pages, Etc.)</b>							
Exr's. Inits.	Ref.	Bibliographic Data					
	AH	Agrawal, Sudhir, Jamal Tamsamani and Jin Yan Tang; September, 1991; <i>Pharmacokinetics, biodistribution, and stability of oligodeoxynucleotide phosphorothioates in mice</i> ; Proc. Natl.Acad.Sci. USA; Vol. 88, pp. 7595-5799					
	AI	Xiao, Bao-Guo and Hans Link; 1997; <i>Mucosal Tolerance: A Two-Edged Sword to Prevent and Treat Autoimmune Diseases</i> ; CLINICAL IMMUNOLOGY AND IMMUNOPATHOLOGY; Vol. 85, No. 2, November, pp. 119-128					
	AJ	Altmann, Daniel M., et al.; March, 1995; <i>The T Cell Response of HLA-DR Transgenic Mice to Human Myelin Basic Protein and Other Antigens in the Presence and Absence of Human CD4</i> ; TRANSPLANTATION BIOLOGY; pp. 867-875					
	AK	Fineschi, Beatrice and Jim Miller; October 1997; <i>Endosomal proteases and antigen processing</i> ; ELSEVIER SCIENCE LTD.; pp. 377-382					
	AL	Agrawal, Sudhir, et al.; October 1988; <i>Oligodeoxynucleoside phosphoramidates and phosphorothioates as inhibitors of human immunodeficiency virus</i> ; PROC.NATL.ACAD.SCI.USA, Vol. 85, pp. 7079-7083					
Examiner					Date Considered		
* Examiner: Initial if citation considered, whether or not citation is in conformance with M.P.E.P. ¶ 609. Draw line through citation (i.e., <del>citation</del> ) if not in conformance and not considered. Include copy of this form with next communication to applicant.							

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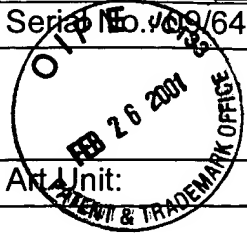
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	<b>BA</b>	Vinitsky, Alexander, et al.; 1994; <i>Inhibition of the Proteolytic Activity of the Multicatalytic Proteinase Complex (Proteasome) by Substrate-Related Peptidyl Aldehydes</i> ; THE JOURNAL OF BIOLOGICAL CHEMISTRY, Vol. 269; pp. 29860-29866	
	<b>BB</b>	Agrawal, Sudhir and John Goodchild; 1987; <i>Oligodeoxynucleoside Methylphosphonates; Synthesis and Enzymic Degradation</i> ; TETRAHEDRON LETTERS, Vol. 28, No. 32, pp. 3539-3542	
	<b>BC</b>	Agrawal, Sudhir and J.-Y. Tang; <i>Efficient Synthesis of Oligoribonucleotide and its Phosphorothioate Analogue Using H-Phosphonate Approach</i> ; pp. 7541-7544	
	<b>BD</b>	Agrawal, Sudhir, et al.; February 1990; <i>Site-specific excision from RNA by RNase H and mixed-phosphate-backbone oligodeoxynucleotides</i> ; PROC. NATL. ACAD. SCI. USA, Vol. 87; pp. 1401-1405	
	<b>BE</b>	Altri, Enrica, et al.; October 1993; <i>CGP 53437, an Orally Bioavailable Inhibitor of Human Immunodeficiency Virus Type 1 Protease with Potent Antiviral Activity</i> ; ANTIMICROBIAL AGENTS AND CHEMOTHERAPY; pp. 2087-2092	
	<b>BF</b>	Androlewicz, Matthew J. and Peter Cresswell; April 1994; <i>Human transporters Associated with Antigen Processing Possess a Promiscuous Peptide-Binding Site</i> ; IMMUNITY, Vol 1; pp. 7-14	
	<b>BG</b>	Bannwarth, Willi; 1988; <i>Solid-Phase Synthesis of Oligodeoxynucleotides Containing Phosphoramidate Internucleotide Linkages and their Specific Chemical Cleavage</i> ; HELVETICA CHIMICA ACTA, Vol. 71; pp. 1517-1527	
	<b>BH</b>	Benjamin, Christopher, W.; et al.; 1998; <i>Caspase Activation in MCF7 Cells Responding to Etoposide Treatment</i> ; MOLECULAR PHARMACOLOGY; pp. 446-450	
	<b>BI</b>	✓ Brömme, Dieter and Hans-Ulrich Demuth; 1994; <i>N,O-Diacyl Hydroxamates as Selective and Irreversible Inhibitors of Cysteine Proteinases</i> ; METHODS IN ENZYMOLOGY, Vol. 244; pp. 671-685	
	<b>BJ</b>	Buttle, David J.; 1994; <i>Affinity Chromatography of Cysteine Peptidases</i> ; pp. 639-649	
	<b>BK</b>	Chen, Jinq-May, et al.; 1997; <i>Cloning, Isolation, and Characterization of Mammalian Legumain, an Asparaginyl Endopeptidase</i> ; THE JOURNAL OF BIOLOGICAL CHEMISTRY, Vol. 272, No. 12; pp. 8090-8098	
Examiner		Date Considered	
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		Art Unit:	
<b>OTHER REFERENCES (Including Author, Date, Title, Pertinent Pages, Etc.)</b>			
Exr's. Inits.	Ref.	Bibliographic Data	
	CA ✓	Chapman, Harold A.; 1998; Endosomal proteolysis and MHC class II function; CURRENT OPINION IMMUNOLOGY; pp. 93-102	
	CB ✓	Chen, Jinq-May, et al.; 1998; <i>Identification of the active site of legumain links it to caspases, clostripain and gingipains in a new clan of cysteine and endopeptidases</i> ; FEBS Letters 441; pp. 361-365	
	CC ✓	Cohen, Gerald, et al.; 1990; <i>Microbial isopenicillin N synthase genes: structure, function, diversity and evolution</i> ; TIBTECH, Vol. 8; pp. 105-111	
	CD ✓	Cosstick, Richard and Joseph S. Vyle; 1989; <i>Solid Phase Synthesis of Oligonucleotides Containing 3'-Thiothymidine</i> ; TETRAHEDRON LETTERS, Vo. 30, No. 35; pp. 4693-4696	
	CE ✓	Cresswell, Peter; February 1996; <i>Invariant Chain Structure and MHC Class II Function</i> ; CELL, Vol. 84; pp. 505-507	
	CF ✓	Dälton, J.P., et al.; 1995; <i>Asparaginyl endopeptidase activity in adult Schistosoma mansoni</i> ; PARASITOLOGY; pp. 575-580	
	CG ✓	Davidson, Howard W. and Colin Watts; July 1989; <i>Epitope-directed Processing of Specific Antigen by B Lymphocytes</i> ; THE JOURNAL OF CELL BIOLOGY, Vol. 109; pp. 85-92	
	CH ✓	Davidson, Howard W., et al.; 1990; <i>Endocytosis, Intracellular Trafficking, and Processing of Membrane IgG and Monovalent Antigen/Membrane IgG Complexes in B Lymphocytes</i> ; THE JOURNAL OF IMMUNOLOGY, Vol. 144; pp. 4101-4109	
	CI ✓	Goodchild, John, et al.; August 1988; <i>Inhibition of human immunodeficiency virus replication by antisense oligodeoxynucleotides</i> ; PROC. NATL. ACAD. SCI. USA, Vol. 85; pp. 5507-5511	
	CJ ✓	Hewitt, Eric W., et al.; 1997; <i>Natural Processing Sites for Human Cathespin E and Cathespin D in Tetanus Toxin</i> ; pp. 4693-4699	
	CK ✓	Jäger, Alfred, et al.; 1988; <i>Oligonucleotide N-Alkylphosphoramidates: Synthesis and Binding to Polynucleotides</i> ; AMERICAN CHEMICAL SOCIETY, pp. 7237-7245	
	CL ✓	Kembhavi, Asha A., et al.; 1993; <i>The Two Cysteine Endopeptidases of Legume Seeds: Purification and Characterization by Use of Specific Fluorometric Assay</i> ; ARCHIVES OF BIOCHEMISTRY AND BIOPHYSICS; pp. 208-213	
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<p>* Examiner: Initial if citation considered, whether or not citation is in conformance with M.P.E.P. ¶ 609. Draw line through citation (i.e., <del>citation</del>) if not in conformance and not considered. Include copy of this form with next communication to applicant.</p>			

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	Filing Date: Sept. 25, 2000	

**OTHER REFERENCES (Including Author, Date, Title, Pertinent Pages, Etc.)**

Exr's. Inits.	Ref.	Bibliographic Data
	DA	Kirschke, Heidrun, et al.; 1998; Lysosomal Cysteine Proteases, Second Edition
	DB	Krantz, Allen; 1994; <i>Peptidyl (Acyloxy)methanes as Quiescent Affinity Labels for Cysteine Proteinases</i> ; pp. 656-671
	DC	Kudo, Jiro, et al.; November 1985; <i>Structure of the human gene encoding the invariant <math>\gamma</math>-chain of class II histocompatibility antigens</i> ; NUCLEIC ACIDS RESEARCH, Vol. 13, No. 24; pp. 8827-8841
	DD	Lanzavecchia, Antonio; 1985; <i>Antigen-specific interaction between T and B cells</i> ; NATURE, Vol. 314, No. 5011; pp. 537-539
	DE	Leit�r, Josef M.E., et al.; 1990; Inhibition of influenza virus replication by phosphorothioate oligodeoxynucleotides; PROC. NATL. ACAD. SCI. USA; pp. 3430-3434
	DF	Lu, Jianyn and Herman van Halbeek; 1996; <i>Complete H and C resonance assignments of a 21-amino acid glycopeptide prepared from human serum transferrin</i> ; CARBOHYDRATE RESEARCH; pp. 1-21
	DG	Lu, Gui-shen, et al.; 1981; <i>Improved Synthesis of 4-Alkoxybenzyl Alcohol Resin</i> ; J. ORG. CHEM., Vol. 46; pp. 3433-3436
	DH	Makoff, Andrew J., et al.; October 1989; <i>Expression of Tetanus Toxin fragment C in E. Coli: Is Purification and Potential Use as a Vaccine</i> ; BIO/TECHNOLOGY VOL. 7; pp. 1043-1046
	DI	Manoury, B�n�dicte, et al.; 1998; <i>An asparaginyl endopeptidase processes a microbial antigen for class II MHC presentation</i> ; NATURE, Vol. 396; pp. 695-699
	DJ	Mik�elian, Ivan and Alain Sergeant; 1992; <i>A general and fast method to generate multiple site directed mutations</i> ; NUCLEIC ACIDS RESEARCH, Vol. 20, No. 2
	DK	Nielsen, John, et al.; 1988; <i>Synthesis and Characterization of Dinucleoside Phosphorodithioates</i> ; TETRAHEDRON LETTERS, Vol. 29, pp. 2911-2914
	DL	O'Sullivan, Deirdre M., et al.; 1986; <i>Structure of the human Ia-associated invariant (<math>\gamma</math>)-chain gene: Identification of 5' sequences shared with major histocompatibility complex class II genes</i> ; PROC. NATL. ACAD. SCI. USA; pp. 4484-4488

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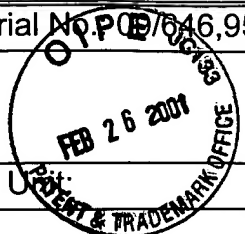
OTHER REFERENCES (Including Author, Date, Title, Pertinent Pages, Etc.)		
Exr's. Inits.	Ref	Bibliographic Data
	EA	
	EB	Palmer, James T., et al.; 1995; <i>Vinyl Sulfones as Mechanism-Based Cysteine Protease Inhibitors</i> ; J. MED. CHEM., pp. 3193-3196
	EC	Pond, Leslie and Colin Watts; 1997; <i>Characterization of Transport of Newly Assembled, T Cell-Stimulatory MHC Class II-Peptide Complexes from MHC Class II Compartments in the Cell Surface</i> ; THE AMERICAN ASSOCIATION OF IMMUNOLOGISTS; pp. 543-553
	ED	Riese, Richard J., et al.; 1996; <i>Essential Role for Cathepsin S in MHC Class II-Associated Invariant Chain Processing and Peptide Loading</i> ; IMMUNITY, Vol. 4; pp. 357-366
	EE	Sharma, K. Krishna, et al.; 1996; <i>Identification of New Lens Protease(s) Using Peptide Substrates Having in Vivo Cleavage Sites</i> ; BIOCHEMICAL AND BIOPHYSICAL RESEARCH COMMUNICATIONS; pp. 365-370
	EF	Shaw, Elliott; 1994; <i>Peptidyl Diazomethanes as Inhibitors of Cysteine and Serine Proteinases</i> ; METHODS IN ENZYMOLOGY; 649-656
	EG	Shaw, Elliott and George D. J Green; 1981; <i>Inactivation of Thiol Proteases with Peptidyl</i> ; METHODS IN ENZYMOLOGY; pp. 820-826
	EH	Shaw, Jeng-Pyng, et al.: 1991; <i>Modified deoxyoligonucleotides stable to exonuclease degradation in serum</i> ; NUCLEIC ACIDS RESEARCH, Vol. 19; pp. 747-750
	EI	Thompson, Robert C.; <i>Peptide Aldehydes: Potent Inhibitors of Serine and Cysteine Proteases</i> ; ENZYMES, ANTIBODIES AND OTHER PROTEINS; pp. 220-225
	EJ	Uznanski, Bogdan, et al.; 1987; <i>Deoxyribonucleoside 3'-Phosphordiamidites as Substrates for Solid Supported Synthesis of Oligodeoxyribonucleotides and their Phosphorothioate and DNA-Triester Analogues</i> ; 1987; TETRAHEDRON LETTERS, Vol. 28; pp. 3401-3404
	EK	Villadangos, José A., et al.; 1997; <i>Degradation of Mouse Invariant Chain: Roles of Cathepsins S and D and the Influence of Major Histocompatibility Complex Polymorphism</i> ; J. EXP. MED., Vol. 186; pp. 549-560
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<b>OTHER REFERENCES (Including Author, Date, Title, Pertinent Pages, Etc.)</b>			
Exr's. Inits.	Ref	Bibliographic Data	
	FA ✓	Watts, Colin; 1997; <i>Capture and Processing of Exogenous Antigens for Presentation on MHC Molecules</i> ; ANNU. REV. IMMUNOL.; pp. 821-850	
	FB ✓	Williams, E. Brady and Kenneth G. Mann; 1993; <i>Peptide Chloromethyl Ketones as Labeling Reagents</i> ; METHODS IN ENZYMOLOGY, Vol. 222; pp. 503-513	
	FC ✓	Woods, Andrea, et al.; July 1994; <i>Human Major Histocompatibility Complex Class II-Restricted T Cell Responses in Transgenic Mice</i> ; J. EXP. MED. Vol. 180; pp. 173-181	
	FD ✓	Yamamoto, Ken, et al.; July 1994; <i>Functional Interaction between Human Histocompatibility Leukocyte Antigen (HLA) Class II and Mouse CD4 Molecule in Antigen Recognition by T Cells in HLA-DR and DQ Transgenic Mice</i> ; J. EXP. MED., Vol. 180; pp. 165-171	
	FE ✓	Cantorna, Margherita T., et al.; 1988; <i>1,25-Dihydroxycholecalciferol Inhibits the Progression of Arthritis in Murine Models of Human Arthritis</i> ; AMERICAN SOCIETY FOR NUTRITIONAL SCIENCES; pp. 68-72	
	FF ✓	Kumar, Vipin, et al.; May 1997; <i>Regulatory T Cells Specific for the Same Framework 3 Region of the Vβ8.2 Chain Are Involved in the Control of Collagen II-induced Arthritis and Experimental Autoimmune Encephalomyelitis</i> ; J. EXP. MED., Vol. 185; pp. 1725-1733	
	FG	Sarin, Prem S., et al.; October 1988; <i>Inhibition of acquired immunodeficiency syndrome virus by oligodeoxynucleoside methylphosphonates</i> ; PROC. NATL. ACAD. SCI. USA, Vol. 85; pp. 7448-7451 [incorrectly listed on original IDS as Vol. 86, pp. 7790-7794].	
	FH	Tang, Jin yan, et al.; 1993; <i>Self-stabilized antisense oligodeoxynucleotide phosphorothioates: properties and anti-HIV activity</i> ; NUCLEIC ACIDS RESEARCH, Vol. 21; pp. 2729-2735	
	FI	Bogyo, Matthew and Hidde L. Ploegh; December 1998; <i>A Protease Draws First Blood</i> ; NEWS AND VIEWS; pp. 625-627	
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	<b>GA</b>	Knight, Andrew M.; et al.; 1997; <i>Antigen endocytosis and presentation mediated by human membrane IgG1 in the absence of the Igα/Igβ dimer</i> , THE EMBO JOURNAL, Vol. 16; pp. 3842-3850	
	<b>GB</b>	Makoff, A.J., et al.; 1989; <i>Expression of tetanus toxin fragment C in E.coli: high level expression by removing rare codons</i> ; NUCLEIC ACIDS RESEARCH, Vol. 17; pp. 10191-10201	
	<b>GC</b>	Makoff, A.J. and M.D. Oxe; 1991; <i>High level heterologous expression in E.coli using mutant forms of the lac promoter</i> , NUCLEIC ACIDS RESEARCH, Vol. 19; pp. 2417-2421	
	<b>GD</b>	Simitsek, Phaedra D., et al.; June 1995; <i>Modulation of Antigen Processing by Bound Antibodies Can Boost or Suppress Class II Major Histocompatibility Complex Presentation of Different T Cell Determinants</i> ; J. EXP. MED., Vol. 181; pp.1957-1963	
	<b>GE</b>	Strubin, Michel; et al.; 1984; <i>The complete sequence of the mRNA for the HLA-DR-associated invariant chain reveals a polypeptide with an unusual transmembrane polarity</i> , THE EMBO JOURNAL, Vol. 3; pp. 869-872	
	<b>GF</b>	<i>Peptimmune and Peptide Therapeutics collaborate on asthma and autoimmune diseases</i> ; PHARMACEUTICAL BUSINESS NEWS, March 25, 1998	
	<b>GG</b>		
	<b>GH</b>		
	<b>GI</b>		
	<b>GJ</b>		
	<b>GH</b>		
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